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Lack of Unity

- 1) Claims 1-17 are under prosecution.
- 2) The instant application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 C.F.R. 1.499, Applicants are required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-15, drawn to an immunogenic composition comprising a GBS saccharide antigen and at least two GBS polypeptide antigens.
 - II. Claim 16, drawn to a method for the therapeutic or prophylactic treatment of GBS infection comprising administering an immunogenic composition of comprising a GBS saccharide antigen and at least two GBS polypeptide antigens.
 - III. Claim 17, drawn to a method for the manufacture of a medicament comprising combining a GBS antigen and at least two GBS polypeptide antigens.
- 3) Inventions I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The special technical feature of the first claimed invention is an immunogenic composition comprising a GBS saccharide antigen and at least two GBS polypeptide antigens. However, such a composition was already suggested in the art by the combined teachings of CHIRON S.P.A (WO 02/34771 A2 – Applicants' IDS) and Michon *et al.* (US 6,372,222 – Applicants' IDS). For example, CHIRON S.P.A. disclosed immunogenic compositions or vaccines comprising two or more of GBS1 through GBS689 proteins or polypeptides, including GBS80 and GBS691 proteins or polypeptides, or fragments thereof and a streptococcal saccharide antigen wherein the saccharide antigen is linked to a carrier protein, such as, tetanus toxoid, diphtheria toxoid, or CRM197. Although CHIRON S.P.A. does not expressly identify the saccharide antigen in the vaccine to be of GBS serotype Ia, Ib, or III, Michon *et al.* taught the use of GBS type II or III saccharide antigen covalently coupled to a bacterial carrier protein, such as, CRM197 or tetanus toxoid, in conjugate vaccines and multivalent vaccines. The instant claims lack an inventive step because it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the generic streptococcal saccharide

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antigen conjugate in CHIRON S.P.A's immunogenic composition or vaccine with Michon's GBS type III or II saccharide antigen conjugate to produce the instant invention with a reasonable expectation of success. Given Michon's teaching that such saccharide antigen conjugates are usable in multivalent vaccines, one of skill in the art would have been motivated to produce the instant invention for the expected benefit of producing a multivalent vaccine, which would advantageously provide GBS saccharide- and GBS protein- or polypeptide-specific immunity against multiple GBS serotypes. Clearly, the special technical feature is not a unifying feature.

4) *Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.*

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the lack of unity/restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

5) The Office has separated product and process claims based on restriction. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

6) In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper lack of unity between product claims and process claims

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may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See 'Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)', 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoiner in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoiner*. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7) This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, the species lack the same or corresponding special technical features as these species do not share a significant common structural element. The species have mutually exclusive structural and/or antigenic or immunogenic characteristics.

(I) GBS saccharide antigen species: (I) Serotype Ia; (II) Serotype Ib; and (III) Serotype III. See claims 1 and 17.

(II) GBS polypeptide antigen combination species: (A) GBS 80 and GBS 104; (B) GBS 80 and GBS 147; (C) GBS 80 and GBS 173; (D) GBS 80 and GBS 276; (E) GBS 80 and 305; (F) GBS 80 and GBS 313; (G) GBS 80 and GBS 322; (H) GBS 80 and GBS 328; (I) GBS 80 and GBS 330; (J) GBS 80 and GBS 338; (K) GBS 80 and GBS 358; (L) GBS 80 and GBS 361; (M) GBS 80 and GBS 404; (N) GBS 80 and GBS 656; (M) GBS 80 and GBS 690; and (N) GBS 80 and GBS 691. See claims 4-9. Claims 1-3 and 10-17 are generic.

(III) Carrier protein species: (a) Tetanus toxoid; (b) Diphtheria toxoid and CRM197; (c) *N. meningitidis* outer membrane protein; (d) Heat shock protein; (e) Pertussis protein; (f) Protein D from *H. influenzae*; (g) Toxin A from *Cl. difficile*; and (g) Toxin B from *Cl. difficile*. See claims 12-15. Claims 1-11 are generic.

(IV) Four viral protein species: (i) VP26; (ii) VP28; (iii) VP19; and (iv) VP24. See claims 13-16, 20 and 26.

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8) Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected species.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

9) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

10) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

11) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be

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reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Shanon Foley, can be reached on (571) 272-0898.

/S. Devi/
S. Devi, Ph.D.
Primary Examiner
AU 1645

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